Aderenza e tollerabilità del vaccino Mpox nelle persone che vivono con HIV: studio monocentrico in un'unità di malattie infettive in Italia.

Exploring mpox vaccination uptake and tolerability among individuals living with HIV: a single-centre study in an infectious diseases unit in Italy.

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Riassunto

Dall'inizio dell'attuale epidemia, nel mondo sono stati registrati circa 89.000 casi di Monkeypox (Mpox). FDA e EMA hanno approvato un vaccino vivo attenuato, non replicante (MVA-BN) per i gruppi a rischio, come gli uomini che hanno rapporti sessuali con uomini (MSM), persone che vivono con HIV (PLWH), sex workers, personale di laboratorio e sanitario. In questo lavoro, vogliamo fornire una panoramica della aderenza del vaccino per mpox nel nostro centro, ed esplorare la sua tollerabilità, a confronto con le persone senza HIV. Abbiamo raccolto retrospettivamente i dati delle persone vaccinate con MVA-BN intradermico in una clinica di malattie infettive a Firenze, Italia, dal 15 settembre al 31 dicembre 2022.

Le informazioni sono state raccolte tramite questionari. I dati sugli eventi avversi sono stati raccolti subito prima della seconda dose, attraverso un apposito questionario. I partecipanti potevano riportare qualunque evento avverso, in qualunque momento, tramite contatto telefonico o e-mail. Inoltre, una seduta vaccinale senza necessità di appuntamento era stata organizzata con una associazione locale (CAT) che assiste donne sex-workers vittime di tratta e sfruttamento sessuale. Complessivamente sono stati vaccinati 200 soggetti: 45,5% (n=91) reclutati nell'ambulatorio HIV.

Le PLWH avevano un'età mediana maggiore, e molte

Abstract

Around 89,000 Monkeypox (Mpox) cases have been registered worldwide since the beginning of the current outbreak. FDA and EMA approved a live attenuated, non-replicating vaccine (MVA-BN) for groups at risk, like men who have sex with men (MSM), people living with HIV (PLWH), sex workers, laboratory, and healthcare workers. We provide an overview of the uptake of mpox vaccination among PLWH in a single center in Italy and explore the nuances of its tolerability compared to individuals without HIV.

We retrospectively collected routine data of people vaccinated with intradermal MVA-BN in a tertiary-level hospital in Florence, Italy, from September 15th to December 31st, 2022. Data were collected from standard pre-vaccination screening questionnaires. The data on adverse events were collected just before the second dose through a dedicated questionnaire. Participants could report any adverse events anytime through phone or email contact. Moreover, a walk-in session for sex workers was organized with a local association (CAT) supporting victims of trafficking/exploitation and sex workers.

A total of 200 subjects were vaccinated: 45.5% (n=91) were recruited in the HIV outpatient clinic.

PLWH had a higher median age, and many people were already vaccinated for smallpox. Overall, 11 people out

erano già vaccinate per il vaiolo. In tutto, 11 persone su 161 (6,8%) non hanno completato il ciclo vaccinale: 5 (4,6%) senza HIV, 6 (6,6%) con HIV (p=0,535). In questo gruppo, 10 su 11 erano sex-workers migranti. Quanto alla tollerabilità del vaccino, tra chi ha riportato eventi avversi dopo la prima dose 26 (28,9%) erano senza HIV18 (30,5%) con HIV (p=0,212). Grazie alla campagna di sensibilizzazione condotta da CAT, nella seduta vaccinale senza appuntamento 19 persone migranti, che si autodefinivano sex-workers, 10 delle quali in precedenza non note al nostro centro, hanno ricevuto il vaccino.
In conclusione, in base alla nostra limitata esperienza, il vaccino Mpox è stato accettato e ben tollerato nelle persone con e senza HIV. Nondimeno, la collaborazione con le associazioni locali e un accesso facilitato al sistema sanitario sono strumenti essenziali per promuovere campagne di screening e di consapevolezza nelle popolazioni vulnerabili, come migranti e sex-workers.

of 161 (6.8%) did not complete the vaccination cycle: 5 (4.6%) were without HIV, 6 (6.6%) were PLWH (p=0.535). Ten out of 11 of the latter group were migrant sex workers. As for vaccine tolerability, individuals who reported adverse events after the first dose were 26 (28.9%) without HIV and 18 (30.5%) with HIV (p=0.212). Thanks to the awareness campaign led by CAT, during the walk-in session 19 individuals who were migrants self-identifying as sex workers, 10 of them previously unknown to our centre, received the vaccine.
In conclusion, based on our limited experience, Mpox vaccination has been accepted and well-tolerated in individuals with and without HIV.
Nevertheless, collaboration with local associations and facilitating access to the healthcare system are essential tools for promoting screening and awareness campaigns in vulnerable populations such as migrants and sex workers.

Introduction

Vaccination plays a pivotal role in preventing and controlling infectious diseases, contributing significantly to public health efforts worldwide.
A group that requires particular attention within this context is individuals living with HIV (PLWH), who face heightened susceptibility to various infections due to compromised immune systems. This has spurred interest in investigating the immunogenicity and safety of vaccines in this group.
Mpox (formerly called monkeypox) is a zoonotic disease caused by an animal Orthopoxvirus endemic to various Central African Countries. It was first recognized during smallpox eradication efforts in 1970. Still, it is only in recent years that epidemics in Nigeria and other African countries demonstrated its potential for rapid human-to-human transmission and allowed to hypothesize transmission through sexual contact (1,2).
In May 2022 a rapid increase in Mpox cases in various non-endemic countries outside of Africa led the World Health Organization (WHO) to declare the outbreak a Global Public Health Emergency. Since the beginning of this large and partly ongoing outbreak around 89.000 cases of Mpox have been reported from 113 WHO Member States (3).
The number of reported cases peaked in August 2022, and has since been steadily decreasing, with an average of 146 cases being observed weekly in the last 12 weeks worldwide and only 1 case reported in Italy in the last two months(4). Unlike what was previously reported about Mpox epidemics in endemic countries, this outbreak largely developed and spread in networks of men who have sex with men (MSM; homosexual or bisexual males) and the primary type of transmission was thought to be direct contact with infected lesions via sexual encounters(5). PLWH were disproportionately affected worldwide by the epidemic, ranging from 38 to 57% of cases in most international cohorts(6); among fatal cases reported in the US until March 2023, 94% were people immunocompromised because of HIV infection with low CD4 cell counts(7).
MVA-BN, a live, non-replicating vaccine by Bavarian Nordic that was initially developed for protecting against a future resurgence of smallpox (8), was approved by the FDA and the EMA for use in preventing Mpox in at-risk groups, which included MSM, PLWH, sex workers, laboratory, and healthcare workers. Following the start of the campaign real-life data about vaccine efficacy started to accumulate, showing an efficacy of around 85% for full vaccination and 75% for partial vaccination in preventing disease in male, female, and children's populations and with no difference between subcutaneous and intradermal administration routes (9–14).
Of note, slightly lower efficacy estimates, around 72% for full vaccination and 55% for partial vaccination, were found in individuals categorized as

immunocompromised (i.e. living with HIV, having another medical condition that weakens the immune response or taking a medicine that weakens the immune response) in a large case-control study in the USA[15]. Early safety data showed a relatively high prevalence of short-term mild adverse events (AEs), ranging from 31 to 53%, the most common being local redness, itching and swelling, but a very low prevalence of systemic and severe (e.g. cardiorespiratory) AEs (13,16).

Data have also been collected about factors influencing vaccination uptake and intention to be vaccinated in various populations (17–19); knowledge of these factors can help in structuring and channelling health promotion efforts in order to increase the impact and equity of vaccines as a public health measure. As an example, a survey conducted in Vancouver, Canada, among 331 vaccine recipients self-identifying as T/GBM (transgender, gay, bisexual or other men who have sex with men), mostly white educated males, found significantly lower percentages of vaccine uptake in individuals who had a lower income, in those who had less knowledge about Mpox transmission and who were less exposed to information promoting the vaccine; more in general, Mpox vaccination acceptance and uptake was found to be patterned on definite social gradients (18).

As far as PLWH are concerned, understanding the factors influencing the uptake of Mpox vaccination among individuals living with HIV and elucidating differences in its tolerability compared to HIV-negative populations are critical steps towards maximization of the benefits of vaccinations for this vulnerable group.

This paper aims to provide an overview of the uptake of Mpox vaccination among people living with HIV in a single center in Italy and to explore the nuances of its tolerability in comparison to individuals without HIV.

Materials and methods

From September 15 to December 31, 2022, we retrospectively collected routine data of people intradermally vaccinated with MVA-BN at the Infectious and Tropical Diseases outpatient clinic, Careggi Teaching Hospital (AOUC), Florence, Italy. Approximately 1,300 PLWH and about 100 people on PrEP regularly refer to the Infectious and Tropical Diseases outpatient clinic.

Demographic and clinical data were collected from standard pre-vaccination screening questionnaires (**Figure 1**).

Information about adverse events after the first dose was collected before the second administration using another self-administered questionnaire (**Figure 2**).

All individuals, including those receiving a single administration, could report any adverse event at any time through a dedicated email and phone number. If the person did not attend the appointment, he or she was called back, and a new appointment was scheduled.

PLWH were recruited among the people in care at the Infectious and Tropical Disease Unit at AOUC. People without HIV were recruited: i) among the persons in follow-up at the sexually transmitted infections (STD)/PrEP clinic of AOUC; ii) among laboratory and healthcare workers; iii) among the general population, by self-application through a dedicated email address/phone number. We offered counselling and an HIV Ab/Ag test to all self-reported HIV-negative individuals who were not already in follow-up at the STD/PrEP clinic, a strategy that other experiences have suggested as a useful way to start a conversation with at-risk individuals about HIV, PrEP and other STDs (20,21).

Vaccination sessions were organized twice a week by appointment only. However, a walk-in session was organized with CAT – Cooperativa Sociale, a local association offering interventions to support female sex workers (both cisgender and transgender) and/or victims of trafficking and exploitation with a harm reduction approach. In particular, the CAT Street Unit, called "Vivian Love", is part of Tuscany's anti-trafficking system (SATIS).

Furthermore, CAT manages the InfoTrans helpdesk, which provides assistance to counteract sexual exploitation and supports access to the healthcare system.

Descriptive analysis was used to illustrate population characteristics and differences. Categorical variables were analysed with X2/Fisher's exact test and continuous variables with the Mann–Whitney test.

The study received the approval by each independent local Ethics Committee (study coordination site protocol number 23013_BIO). All the patients provided written informed consent for the use of their data for research purposes.

To be filled by the vaccinee and reexamined with healthcare professionals who overview vaccination.

NAME AND SURNAME	PHONE NUMBER		
	YES	NO	DON'T KNOW
Are you ill right now?			
Are you feverish?			
Do you have spots, pimples or other active lesions on your skin or any other part of your body (anal and genital area included)?			
Do you suffer from any allergies? If yes, specify:…… ……..			
Do you suffer from latex allergy, food allergy (e.g. chicken, eggs), drug allergy (e.g. ciprofloxacin, gentamicin) or allergy to vaccine components? If yes, specify:…… ……..			
Have you ever had a severe adverse reaction to a vaccine?			
Have you ever suffered from pericarditis/myocarditis (an illness resulting from inflammation in the cardiac muscles)?			
Do you suffer from any heart or pulmonary disease, asthma, kidney disease, diabetes, anemia or other blood diseases? If yes, specify: …… ……..			
Do you suffer from disorders of hemostasis and coagulation and/or do you take anticoagulant drugs?			
Have you ever suffered from atopic dermatitis or other skin diseases? If yes, specify: …… ……..			
Do you have a condition that compromises your immune system (examples: cancer, leukemia, lymphoma, HIV/AIDS, transplant)? If yes, specify: …… ……..			
In the last three months, did you take drugs that weaken your immune system (examples: prednisone or other corticosteroids) or antitumoral drugs? Did you receive radiotherapist treatment? If yes, specify: …… ……..			
In the last year, did you receive a blood transfusion or treatment with i.v. Immunoglobulins? If yes, specify: …… ……..			
In the last month, have you been in contact with a person who contracted the mpox virus?			
In the last month, did you travel internationally? If yes, specify:…… ……..			
In the last four weeks, did you receive any vaccinations? If yes, which one/s? …… ……			
Are you planning to vaccinate against COVID-19 in the next four weeks?			
Have you already received a dose of Jynneos or another vaccine against smallpox or monkeypox? If yes specify the name of the vaccine (if known) and date of vaccination……			
For women: Are you pregnant or thinking about becoming pregnant in the month following the first or the second administration of the vaccine?			
For women: Are you currently breastfeeding?			

Specify all the drugs you are currently taking, in particular anticoagulant drugs; remember to specify nutraceuticals, vitamin supplements, mineral supplements or other alternative medications you might eventually be taking.

Figure 1. Screening pre-vaccination questionnaire administered to individuals before vaccination (English version).

DATE

To be compiled by the vaccinee:

Name: Surname: Participation in clinical study

Date of birth: ID: Waiting time

DATE OF FIRST DOSE ADMINISTRATION	
BATCH	
SITE OF INOCULATION	
SITE	Ambulatorio Malattie Infettive, PAD 15, Piastra dei Servizi, Piano Terra, AOU CAREGGI
In order to cancel the appointment or information on the vaccine, please write to:	

Your second dose of vaccine will be administered on …… at the same time.

AFTER THE FIRST DOSE, YOU EXPERIENCED:

- ☐ No adverse event
- ☐ Immediate (<4 hours) local reaction (pruritus, erythema, edema at the inoculation site)
- ☐ Immediate (<4 hours) systemic reaction (generalized pruritus, diffuse erythema, urticaria or angioedema)
- ☐ Delayed (>4 hours) local reaction (pruritus, erythema, edema at the inoculation site)
- ☐ Delayed (>4 hours) systemic reaction (generalized pruritus, diffuse erythema, urticaria or angioedema)

VARIATIONS REGARDING INITIAL QUESTIONNAIRE

- ☐ No variation
- ☐ Variation (specify variations)

……

……

……

Signature of vaccinee_____

Signature of health professional_____

Figure 2. The questionnaire administered to individuals at our centre after the first dose (English version).

Results

During the study period 200 individuals were vaccinated against Mpox at our centre; 91 (45.5%) were living with HIV. Their baseline characteristics are synthetized in **Table 1**.

Table 2 presents the ART regimens at the time of vaccination.

We found a slightly higher prevalence of transgender women in the HIV group (n=15; 16.5%)

	WITHOUT HIV (n=109)	WITH HIV (n=91)	p
Gender; N (%)			0.056
Man	93 (85.3)	76 (83.5)	
Woman	5 (4.6)	0	
Transgender woman	11 (10.1)	15 (16.5)	
Median age in years [IQR]	37 [31-44]	43 [38-53]	<0.001
Country of Origin; N (%)			0.226
Italy	88 (80.7)	66 (72.5)	
Peru	11 (10.9)	14 (15.4)	
Brazil	5 (4.6)	2 (2.2)	
Other	5 (5.6)	9 (9.9)	
Self-defining MSM	85 (77.9)	78 (85.7)	0.563
Self-defining Sex worker	11 (10.1)	13 (14.3)	0.563
For PLWH: CDC stage C3 at diagnosis (available for 62 out of 91 records) (%)	\	3 (4.8)	
For PLWH: Median years from HIV diagnosis (available for 79 out of 91 records) [IQR]	\	8 [0-37]	
For PLWH: Median CD4+ T cells nadir (cells/mm^3) (available for 61 out of 91 records) [IQR]	\	392 [12-1341]	
For PLWH: Median HIV RNA copies zenith (logs/mL) (available for 53 out of 91 records) [IQR]	\	5.1 [2.1-7]	
N° of expected doses; N (%)			0.003
1 dose	13 (11.9)	26 (28.6)	
2 doses	96 (88.1)	65 (71.4)	
Number of individuals who did not complete the second dose; N (%)	5 (4.6)	6 (6.6)	0.535
Adverse event (AE) after the first dose*; N (%)			0.212
Local	26 (28.9)	16 (27.1)	
Systemic	0	2 (3.4)	
Median duration of local skin reactions (itching, oedema, pain) [IQR]	7 [4-12]	6 [4-14]	0.343
Reported any allergies; N (%)			0.449
None	90 (82.6)	73 (80.2)	
Environmental	15 (13.8)	11 (12.1)	
Pharmacological	4 (3.7)	7 (7.7)	
Cardiovascular diseases; N (%)	5 (4.6)	5 (5.5)	0.769
Asthma; N (%)	5 (4.6)	4 (4.4)	0.948
Skin disorder; N (%)	11 (10.9)	5 (5.5)	0.233
Vaccination type received between 15 to 30 days before vaccination for Mpox; N (%)	12 (11)	7 (7.7)	N/A
HPV	1	2	
Meningococcal vaccine	0	1	
HAV	2	2	
Chickenpox	1	0	
Flu	1	1	
SARS-CoV-2	7	1	

**Evaluated only in the person who got two doses (n=150).*
Persons with only one dose were excluded.

Table 1. Baseline characteristics of a group of people vaccinated for Mpox from 15/09/2022 to 31/12/2022 at the outpatient clinic of the Infectious and Tropical Diseases Unit, Careggi Teaching Hospital, Florence, Italy.

ART regimen	N (%) (total individuals with HIV, n=91)
BIC/TAF/FTC	26 (28.6)
DTG/3TC	24 (26.3)
DOR/TDF/3TC	13 (14.3)
TAF/FTC/RPV	10 (11)
DTG/RPV	5 (5.5)
DRV/c/TAF/FTC	4 (4.4)
DTG/ABC/3TC	2 (2.2)
TDF/FTC/EFV	2 (2.2)
ATZ/c/TAF/FTC	1 (1.1)
DRV/c + RPV	1 (1.1)
DTG + DOR	1 (1.1)
DTG + DRV/c	1 (1.1)
TAF/FTC/EVG/c	1 (1.1)

Table 2. ART regimens in individuals with HIV vaccinated against Mpox from 15/09/2022 to 31/12/2022 at the Infectious and Tropical Diseases Unit outpatient clinic, Careggi Teaching Hospital, Florence, Italy.

compared to the non-HIV group (n=11; 10.1%. p=0.056).

Regarding nationality, the majority were Italian, followed by Peruvian and Brazilian nationalities, with no difference between the two groups. The HIV group had a higher median age (43; IQR=38-53 years) and, consequently, a higher prevalence of individuals already vaccinated with smallpox (26; 28.6% vs 13; 11.9%, respectively). The comorbidities rate was overall low in people with and without HIV.

The proportion of individuals self-identifying as MSM and sex workers was not different in the two populations (77.9% and 10.1% in the non-HIV group vs. 85.7% and 14.3% in the HIV group). Thanks to the awareness campaign led by CAT, during the walk-in session 19 individuals who were migrants self-identifying as sex workers, 10 of them previously unknown to our centre, received the vaccine.

Despite numerous attempts by health professionals to make them adhere to the vaccination campaign, 11 individuals out of 161 (6.8%) did not return for the second dose: 5 (4.6%) were individuals without HIV, 6 (6.6%) were individuals with HIV (p=0.535).

Nationality; N (%)	
Peru	9 (81.8%)
Italy	1 (9.1%)
Brazil	1 (9.1%)
Age; Median [IQR]	37 [31-40]
HIV infection; N (%)	6 (54.5%)
Self-defining MSM; N (%)	1 (9.1%)
Self-defining Sex worker; N (%)	10 (90.9%)
Comorbidities; N (%)	1 (9.1%)
Allergies; N (%)	2 (18.2%)

Table 3. Baseline characteristics of the group of people (n=11) who did not complete the full vaccination cycle with the MVA-BN vaccine.

Among the 11 individuals who didn't complete the cycle, most of the HIV-negative ones were transgender women who belonged to a distinct population of South American (Peru) sex workers living in the same community and were recruited through collaboration with CAT; on the other hand, PLWH who didn't complete the cycle were patients who were routinely followed at our centre and who decided to spontaneously interrupt vaccination, even though advised against this decision. The clinical-demographic characteristics of the individuals who did not complete the full vaccination are presented in **Table 3**.

As for vaccine tolerability, adverse events (AEs) after the first dose were observed in 26 (28.9%) individuals without HIV and 18 (30.5%) individuals living with HIV (p=0.212); the local and systemic reactions reported in the questionnaires after the first dose showed no differences between groups. All AEs were mild, with a median duration of 7 days in both groups; we received no reports of AEs via email or phone.

Notably, about 20% of the population in both groups had a history of environmental/food or drug allergies; however, unlike other studies, we could not find a significant association between the development of local AEs and pre-existing allergies (p=0.423)[13]. Of note, among the individuals monitored at our clinic (PrEP and HIV), none contracted Mpox in the months following vaccination.

Discussion

Our results did not show significant differences in Mpox vaccination uptake and tolerability between individuals with and without HIV infection. The uptake of the two vaccine doses was mostly good, with most HIV and non-HIV individuals being fully vaccinated. A significant finding was that most of the individuals who failed to receive all the expected vaccine doses belonged to the same marginalized community of migrant transgender sex workers, who also suffered from a high burden of HIV infection; this occurred despite our special attention to this issue. We believe that the reason why eleven individuals failed to return for the second dose can mainly be attributed to personal and organizational reasons. During the campaign, the vaccination sessions were organized by appointments and in multiples of five people to optimize intradermal administration of the vaccine and prevent wastage (in fact, using the MVA-BN through the intradermal route, it was possible to administer up to 5 doses per vial). We hypothesize that these migrant sex workers, due to their vulnerable condition, are compelled to adopt a stressful and irregular way of life and, for this reason, they were not always able to respect the scheduled appointments. For them, therefore, their own health is not at the top of the hierarchy of needs (22). Consequently, since the number of Mpox cases and the fear of contracting the infection decreased, other priorities might have taken precedence in their lives. At a level of healthcare policies, however, the lower uptake in vulnerable populations is probably also due to lack of institutional prioritization of sex workers within the healthcare system, in particular of female cisgender or transgender sex workers.

As others have suggested, this evident gap in uptake should be addressed through the implementation of further education and health promotion interventions targeted at these more fragile populations and through the adoption of a low-threshold, barrier-free approach to vaccination, including sex-worker vaccination policies and mobile health services (23). In our small experience, collaboration with local associations like CAT and the establishment of walk-in vaccine sessions have been beneficial strategies to reach this particular sex worker community, even if with only partial vaccination.

Regarding tolerability, the short-term safety profile was overall very good, in accordance with available evidence (13). No significant differences in the prevalence of AEs were recorded between PLWH and people without HIV; the same result was observed in a large study from Australia, where the same prevalence of local AEs after the first dose of vaccine was found in the general study population and in a subgroup of 310 patients with immunodeficiency and/or HIV13. The burden of AEs was almost entirely attributable to local and mild ones, and we didn't observe any serious adverse events.

Although not one of the objectives of this study, regarding the effectiveness of the vaccination, we did not observe any cases of Mpox among the vaccinated individuals who were followed-up continuously at the Infectious and Tropical Diseases Clinic of AOU Careggi (PrEP and HIV). This finding can be attributed to the vaccination's high effectiveness, as reported in other studies (9–12,14), and to the changing Italian epidemiological scenario, which has seen a sharp reduction in cases starting October 2022.

This study has several limitations, mainly due to its small sample size and single-centre nature. Additionally, although all participants could report any adverse events at any time through a dedicated e-mail address, active assessment of tolerability through questionnaires was performed only in individuals receiving two vaccine doses and only in the interval between the first and the second dose. This might have led to an underestimation of AEs. In particular we did not actively collect AEs in participants who failed to complete the cycle, in those who needed only one dose of vaccine because of a previous smallpox vaccination and in participants who manifested AEs after the second dose. However, one strong point of this study is that it reports one of the first Italian experiences on the tolerability differences of the Mpox vaccination between groups of individuals with and without HIV.

In conclusion, based on our limited experience, Mpox vaccination has been accepted and well-tolerated in individuals with and without HIV. However, the few cases that have not completed the vaccination cycle are almost all migrants and sex workers. Nevertheless, collaboration with local associations and facilitating access to the healthcare system are essential tools for promoting screening and awareness campaigns in vulnerable populations such as migrants and sex workers. ■

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